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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,478	11/14/2000	James A. Laugharn Jr.	07985-012002	6793

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Fish & Richardson
225 Franklin Street
Boston, MA 02110-2804

EXAMINER

LEWIS, PATRICK T

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 07/15/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/530,478

Applicant(s)

LAUGHARN JR. ET AL.

Examiner

Patrick T. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9,72,73,75,76,78-80,82-84,91,92 and 98 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 72,73,79,80,82,91,92,98 and 99 is/are rejected.
- 7) ☒ Claim(s) 75,76,78,83 and 84 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Applicant's Response dated May 16, 2003

1. In the Response filed May 16, 2003, claims 72, 91, and 98 were amended. Applicant presented arguments directed to the rejection of claims 72-73, 79-80, 82, 91-92, and 98-99 under 35 U.S.C. 103(a). Claims 72-73, 75-76, 78-80, 82-84, 91-92, and 98-99 are pending. An action on the merits of claims 72-73, 75-76, 78-80, 82-84, 91-92, and 98-99 is contained herein below.
2. The rejection of claims 72-73, 75-76, 78-80, 82-84, 91-92, and 98-99 under 35 U.S.C § 103(a), is maintained for the reasons of record set forth in the Office Action dated December 18, 2002.
3. The objection to claims 75-76, 78, and 83-84 is maintained for the reasons set forth in the Office Action dated December 18, 2002.

Objections/Rejections Set For the in Office Action dated December 18, 2002

4. Claims 72-73, 79-80, 82, 91-92, and 98-99 were rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Frantz et al. U.S. 5,536,496 (Frantz) and Chen et al. U.S. Patent 5,104,674 (Chen).

Claims 72-73, 79-80, and 82 are drawn to a method of releasing molecules from cells, the method comprising: exposing the cells to an elevated pressure of at least 500 psi in a pressure chamber to form lysed cells whereby the molecules are released from the lysed cells within the pressure chamber. Claims 91-92 are drawn to a method of

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isolating a biological component from a liquid sample, the method comprising: exposing the sample to an elevated pressure in a pressure chamber, the elevated pressure being sufficient to maintain the sample in a liquid state at a subzero temperature; while maintaining the elevated pressure, reducing the temperature of the sample to the subzero temperature; and while maintaining the elevated pressure and the subzero temperature, isolating the biological component from the sample. Claims 98-99 are drawn a method for the isolation of molecules from cells, the method comprising: exposing the cells to a pressure of at least 500 psi in a pressure chamber to form lysed cells; and separating the molecules from the lysed cells within the pressure chamber.

Frantz teaches a method of lysing bacterial cells (column 7, lines 1-21). Frantz teaches the use of a GAULIN model 15M laboratory homogenizer as the apparatus to lyse cells and release their cellular contents. Bacterial cells in the culture fluid are lysed by continuous passage through the pressure chamber of the homogenizer. This subjects the cells to an immediate pressure drop from between an initial pressure drop of between 2000 and 5000 psi to ambient pressure of 15 psi. The lysed cells are aseptically deposited into another closed container. The lysate is then clarified by sequential steps of centrifugation and/or microporous filtration.

Frantz differs from the instantly claimed invention in that Frantz does not teach isolating molecules from the lysed cells within the pressure chamber. Frantz is silent on the temperature at which the process is performed. These deficiencies would have been obvious to one of ordinary skill in the art in view of Chen.

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Chen teaches the microfragmentation of ionic polysaccharide/protein complex dispersions (column 11, lines 2-34). Chen teaches that effective results are achieved using a CD150 or MC15 cell disruptor using a knife edge homogenization element within a closely surrounding impact ring (Gaulin Corp.) at an inlet pressure of at least about 3000 psig to obtain microfragments smaller than fifteen microns. The dispersion may be passed through a cell disruptor or other high shear zone, a sufficient number of times to provide a desired particle size. The shearing zone may be a high pressure, fluidic, acoustic or mechanically driven mill zone, such as a colloid or pin mill high shear zone (column 22, lines 22-41). Within the zone, the ionic polysaccharide/protein solution is acidified in order to initiate the formation of a complex precipitate under high shear conditions.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Frantz and Chen to arrive at the instantly claimed method. Frantz teaches a method of lysing bacterial cells via continuous passage through the pressure chamber of a homogenizer. It would have been obvious to isolate or separate the molecules from the lysed cells within the pressure chamber since Chen teaches a very similar method in wherein precipitation occurs within the pressure chamber of a homogenizer. Optimization of temperature ranges is seen to be within the purview of the skilled artisan, as differences in temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such temperature is critical. One would have been motivated to do so in order to produce free toxoid and whole bacterin-toxoid vaccine compositions.

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5. Claims 75-76, 78, and 83-84 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

6. Applicant's arguments filed May 16, 2003 have been fully considered but they are not persuasive.

Applicant argues that the instantly claimed method requires isostatic pressure while the art of record teaches the use of a shearing force to release the cellular contents, in effect teaching away from the instantly claimed invention. The examiner respectfully disagrees.

Frantz teaches a method of lysing bacterial cells which is within the scope of the instantly claimed method when viewed in combination with Chen. The type of pressure required to lyse the cell in the instantly claimed invention is not seen as a critical limitation. There is a reasonable expectation of success for using different types of pressure to accomplish the same effect. Applicant should provide adequate support in the form of a declaration or some other evidence to support the criticality of the type of pressure employed to lyse the cells in the instant process. As presently set forth, and when the record and prior art are considered in toto, it is clear that the art of record does indeed render the instantly claimed invention *prima facie* obvious.

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Conclusion

7. Claims 72-73, 75-76, 78-80, 82-84, 91-92, and 98-99 are pending. Claims 72-73, 79-80, 82, 91-92, and 98-99 are rejected. Claims 75-76, 78, and 83-84 are objected to. No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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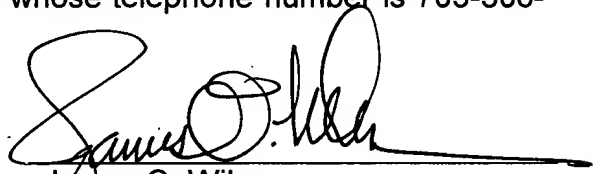
Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD
Examiner
Art Unit 1623



James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

ptl
July 9, 2003